IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

FERRING PHARMACEUTICALS, INC.,

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Plaintiff,

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v. Civil Action No. AW-09-02601

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RIVER'S EDGE PHARMACEUTICALS, LLC,

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Defendant.

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MEMORANDUM OPINION

Pending before this Court is Defendant's Motion to Dismiss (Doc. No. 5) in this Lanham Act claim arising from Defendant's false or misleading commercial advertising of the drug RE Methylphen. The Court held a hearing on Defendant's motion on August 2, 2010. For the reasons discussed below, the Court DENIES Defendant's Motion to Dismiss.

FACTUAL BACKGROUND

Ferring Pharmaceuticals, Incorporated, ("Plaintiff" or "Ferring") is a Delaware corporation with offices in New Jersey and is engaged in the business of manufacturing and selling prescription drugs. River's Edge Pharmaceutical, LLC, ("Defendant" or River's Edge") is also engaged in the pharmaceutical industry and transacts business in Maryland.[1] Plaintiff manufactures the drug Prosed, which is "a urinary antiseptic prescription drug product" that is administered as an oral tablet. (Compl. ¶ 7.) Defendant has a purportedly similar drug called RE Methylphen. Neither Prosed nor RE Methylphen are drugs listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the "Orange Book", which is a list of drugs approved by the Food and Drug Administration ("FDA") "for safety and effectiveness"

[1] The record is silent as to where Defendant is incorporated. Otherwise, Defendant did not contest that venue in this Court was inappropriate.

and also contains therapeutic equivalents of these drugs. Food and Drug Admin., *Approved Drug Products with Therapeutic Equivalence Evaluations* i (30th Ed. 2010).

Plaintiff alleges that Defendant "markets RE Methylphen as a lower cost alternative to [Plaintiff's] brand name product [Prosed]" when Defendant's drug is by no means equivalent to Plaintiff's product and that such marketing "includes statements on its label, packaging insert, and elsewhere that RE Methylphen contains the same amounts of the same five active ingredients as in Prosed." (*Id.* at ¶ 10.) The Plaintiff does not provide a copy of any of these alleged statements, other than some general language from Defendant's website, which does not contain any reference to Plaintiff or the particular drug products. Moreover, Plaintiff contends that Defendant makes such statements "knowing that drug data publishing services such as First Databank Medi-Span, and RedBook" rely on "a products label and package insert" to list drugs as generics of others. (*Id.*) Plaintiff also alleges that Defendant knows that this grouping of RE Methylphen with Prosed will also result in pharmaceutical reference books, called drug formularies, to represent that "RE Methylphen can be substituted for Prosed." (*Id.* at ¶ 11.) In fact, Plaintiff has provided examples of three drug formularies listing RE Methylphen as the generic of Prosed, namely a June 2009 ConnectiCare Notice, a May 2009 Blue Cross & Blue Shield of Mississippi Notice, and a September 2009 notice from Blue Cross of Northeastern Pennsylvania. Plaintiff contends that Defendant knows its marketing is misleading because it fails to include a disclaimer, which is posted on Defendant's website, in the labeling and packaging inserts of RE Methylphen. This disclaimer states, "Even when a River's Edge product is labeled as containing the same active ingredients, they may be subject to different potency and dissolution specifications . . ." (*Id.* at ¶¶ 12-15.) Plaintiff asserts that Defendant failed to include

this disclaimer in its marketing because it would prevent the drug data publishing services from listing RE Methylphen as a generic for Prosed.

Plaintiff claims that physicians, pharmacists, patients, and others in the pharmaceutical industry rely on the drug formularies and other drug data publishing services in making decisions about which drugs can be substituted for another as permitted under their respective state laws. Plaintiff also alleges that doctors, pharmacists, patients, and drug data publishing services, among others, also rely on manufactures to correctly identify the active ingredients, as well as, the amounts of each active ingredient in the prescription drug product. Plaintiff claims that it conducted laboratory testing of RE Methylphen and the results indicated that it "did not fall within the clinically acceptable range for a generic equivalent with respect to [four][2] of the [five] ingredients" because it contained higher amounts of those four ingredients.[3] (*Id.* at ¶ 19.) In other words, Plaintiff is claiming that RE Methylphen actually contains more of the four active ingredients than contained in Prosed; and therefore, Defendant's representations that RE Methylphen has the same amount of the same active ingredients as Prosed is false or misleading. Thus, Plaintiff asserts that RE Methylphen is "not a generic version of Prosed and is not equivalent," and contends that Defendant's marketing of its products contains "false and misleading representations of facts in commercial advertising and promotion that misrepresents the nature, characteristics, and qualities of [the two companies] products in violation of Section 43(a) of the Lanham Act . . . ." (*Id.* at ¶ 19, 21). As a result, Plaintiff alleges that it has suffered a loss of sales and its goodwill has been damaged and seeks injunctive and monetary relief.

[2] These four active ingredients are Methenamine, Phenyl salicylate, Hysocyamine sulfate, and Methylene blue.
[3] At the hearing, Plaintiff explained that each batch of Prosed is tested to confirm that the product contains 90–110% of each ingredient. Plaintiff's testing of RE Methylphen revealed that the amount of those same ingredients in RE Methylphen ranged from 120–185%.

STANDARD OF REVIEW

The purpose of a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) is to test the sufficiency of the plaintiff's complaint. *See Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999). Generally, a complaint need only satisfy the simplified pleading standard of Rule 8(a), *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 513 (2002), which requires a short and plain statement of the claim showing that the pleader is entitled to relief. Fed. R. Civ. P. 8(a)(2). Nevertheless, the Supreme Court has directed courts that Rule 8 still requires a showing, of "enough facts to state a claim to relief that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 n.3 (2007). In its determination, the Court must consider all well-pled allegations in a complaint as true, *Albright v. Oliver*, 510 U.S. 266, 268 (1994), and must construe all factual allegations in the light most favorable to the plaintiff. *See Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783 (4th Cir. 1999). The Court need not, however, accept unsupported legal allegations, *Revene v. Charles County Comm'rs*, 882 F.2d 870, 873 (4th Cir. 1989), legal conclusions couched as factual allegations, *Papasan v. Allain*, 478 U.S. 265, 286 (1986), or conclusory factual allegations devoid of any reference to actual events, *United Black Firefighters v. Hirst*, 604 F.2d 844, 847 (4th Cir. 1979). In sum, factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact). *Twombly*, 550 U.S. at 555 (citations omitted).

ANALYSIS

In relevant part, § 43(a) of the Lanham Act provides that any person who, on or in connection with any goods or services, . . . , uses in commerce, . . . , any . . . false or misleading description of fact, or false or misleading representation of fact," which "in commercial advertising or promotion, misrepresents the nature, characteristics, [or] qualities, . . . of his or her

or another's person's goods, . . ." is liable to any person alleging damage because of such false or misleading advertising. 15 U.S.C. § 1125(a) (2006). In the Fourth Circuit, to establish a Lanham Act claim, the plaintiff must show the following:

> (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of [the] goodwill associated with its products.

Pediamed Pharms., Inc. v. Breckenridge Pharm., Inc., 419 F. Supp. 2d 715, 728 (D. Md. 2006) (citation omitted).

In satisfying the first element, the plaintiff must show that "the contested statement or representation [is] either false on its face or, although literally true, likely to mislead and to confuse consumers given the merchandising contexts." *Id.* (citation omitted). A plaintiff need not provide evidence of consumer deception where the advertisement is false on its face. *Id.* On the other hand, where the "plaintiff's theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged [advertisements] tend to misled or confuse consumers." *Id.*

Plaintiff alleges that Defendant's marketing of RE Methylphen as having the same amounts of the same active ingredients as contained in Prosed has misled drug data publishing services to list RE Methylphen as a generic for Prosed, which further misleads the doctors,

pharmacists, patients, and others in the pharmaceutical industry, who rely on the accuracy of these drug reference books, to believe that RE Methylphen is a substitute for Prosed.[4]

River's Edge contends that the Plaintiff's Lanham Act claim is precluded by the Food, Drug, and Cosmetics Act ("FDCA"). Defendant also asserts that Plaintiff's failure to provide a statement or copy of the advertisement allegedly claiming that RE Methylphen has the same amount of the same active ingredients as Prosed is insufficient to plead a cognizable claim under the Lanham Act. Lastly, Defendant argues that Plaintiff's Complaint fails to set forth a cognizable claim because it has failed to plead the amounts of each ingredient in Plaintiff's drug and failed to allege that there is a legally significant difference in the strengths of the ingredients in the parties' respective products under any established standard. The Court will address the claim preclusion argument first.

I. Claim Preclusion

All actions seeking to enforce the provisions of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Courts have interpreted this statute to mean that there is no private right of action to enforce the provisions of the FDCA. *Sanderson Farms, Inc. v. Tyson Foods, Inc.*, 549 F. Supp. 2d 708, 718-19 (D. Md. 2008) (citations omitted). Of relevance in this case is the FDA's enforcement power to regulate "adulterated drugs," which are drugs whose "strength differs from, or its quality or purity falls below, that which it purports or is represented to possess," § 351(b-c), and misbranded drugs, which are drugs whose labeling is

[4] As the Defendant argues, to the extent that Plaintiff is solely asserting that the product label of RE Methylphen is literally false, namely that RE Methylphen does not contain the amount of active ingredients that the label says that it contains, then such a claim is in essence a mislabeling or misbranding claim which is precluded by the FDA's exclusive jurisdiction. *Pediamed*, 419 F. Supp. 2d at 726 n.14. However, as Defendant acknowledged during the hearing, Plaintiff is also alleging that Defendant's drug product contains higher amounts of the same active ingredients as listed on Plaintiff's label in the same quantities, which Plaintiff claims has misled those in the pharmaceutical industry to believe that RE Methylphen can be substituted for Prosed. As the Court discusses below, it is not prepared to rule that this second allegation is precluded by the FDA and its implementing regulations at this stage in the litigation.

"false or misleading in any particular," § 352. As this Court has recognized, given the Lanham Act and FDCA's overlapping regulation of false labeling, "federal courts have struggled" to distinguish between cases that assert valid Lanham Act claims and those that allege "Lanham Act violations as a means to achieve private enforcement of the FDCA." *Sanderson*, 549 F. Supp. 2d at 719. "Courts have come to the general conclusion that the FDA's enforcement of the FDCA is primarily concerned with the safety and efficacy of new drugs, while the Lanham Act is focused on the truth or falsity of advertising claims." *Axcan Scandipharm Inc. v. Ethex Corp.*, 585 F. Supp. 2d 1067, 1075 (D. Minn. 2007) (quoting *Solvay I*, No. Civ. 03-2836 JRTFLN, 2004 WL 742033, at *3 (D. Minn. 2004). In *Pediamed*, this Court reiterated that "a claim cannot stand if it comes 'too close to the exclusive enforcement domain of the FDA,'" but on the other hand, the FDCA does not "eviscerate a Lanham Act or related common law claim over which the agency has no jurisdiction." 419 F. Supp. 2d at 723 (citation omitted).

In distinguishing between permissible and impermissible Lanham Act claims involving the marketing of drug products, courts have decided that claims requiring the interpretation or application of the FDCA, or other FDA implementing regulations, are precluded from being brought by private litigants. *Pediamed*, 419 F. Supp. 2d at 715. A review of the case law suggests that not every claim requiring an interpretation of the FDCA is impermissible; instead, only claims that "require interpretation of a matter that is *exclusively* within the jurisdiction and expertise of the FDA and FDCA" are improper attempts to "use the Lanham Act as a backdoor to private enforcement." *Axcan*, 585 F. Supp. 2d at 1075 (quoting *Solvay I*, 2004 WL 742033, at *2-3) (emphasis added). In fact, some courts have held that "false statements are also actionable even if their truth may be generally within the purview of the FDA," either "through reference to standards other than those of the FDA," or where a party merely relies on clearly established

FDA standards or requirements to demonstrate the falsity or deceptiveness of a statement in a commercial advertisement. *See POM Wonderful LLC v. Ocean Spray Cranberries, Inc.*, 642 F. Supp. 2d 1112, 1118 (C.D. Cal. 2009); *Axcan*, 585 F. Supp. 2d at 1074-1076 (citing *Solvay I*, 2004 WL 742033, at *2-3).

Defendant has interpreted Plaintiff's Complaint as alleging that Defendant advertised RE Methylphen as an equivalent to or generic to Plaintiff's drug, which Defendant argues is precluded under the Lanham Act because it would require the Court to establish a "clinically acceptable range for a generic equivalent of a drug that has not been approved by the [FDA]." (Def.'s Mem. Supp. Dismiss 2.) However, Plaintiff's Complaint does not appear to allege that Defendant has made an affirmative false statement of generic equivalence between the drugs. In any event, the case law is relatively consistent in holding that claims that a competitor has falsely advertised its product as the generic of another drug, especially where the drugs are not subject to FDA approval, are permissible Lanham Act claims and are not barred by the FDA or FDCA. *See e.g. Mylan Labs. Inc. v. Matkari*, 7 F.3d 1130 (4th Cir. 1993); *Graceway Pharms., LLC v. River's Edge Pharms., LLC.*, No. 2:08-CV-0067-RWS, 2009 U.S. Dist. LEXIS 103589, at *26-27 (N.D. Ga. Nov. 6, 2009); *Pediamed*, 419 F. Supp. 2d at 725; *Healthpoint, Ltd. v. Straus Pharms. Inc.*, 273 F. Supp. 2d 769, 792 (W.D. Tex. 2001). *Contra Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F. Supp. 2d 1055 (E.D. Mo. 2002). In particular this Court in *Pediamed* was persuaded by the reasoning articulated in *Schwarz* and *Solvay* which essentially held that absent any evidence that the FDA has sought to investigate or to verify claims of bioequivalence, pharmaceutical equivalence, and therapeutic equivalence, there was no basis for finding that FDA approval was required before a drug manufacturer could make such a claim. *See* 419 F. Supp. 2d at 725 (citing *Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F. Supp. 2d 967,

975 (E.D. Wis. 2005); *Solvay II*, 298 F. Supp. 2d 880, 884 (D. Minn. 2004)). Neither of the drug products in this case are listed in the FDA's Orange book, nor is there any evidence that these drugs were required to apply for FDA approval. Thus, to the extent that Plaintiff's Complaint seeks to allege that Defendant has made false representations of generic equivalence between the two drugs, such a claim is not precluded by the FDA or FDCA from being brought as a Lanham Act claim.[5]

Plaintiff asserts that its Complaint alleges that Defendant has marketed "RE Methylphen as a lower cost alternative" to Prosed although RE Methylphen "is no respect equivalent to or the same as Prosed" and that Defendant has falsely marketed RE Methylphen, in "labels, packaging inserts, and elsewhere, as containing the same amounts of the same active ingredients as Prosed," which according to Plaintiff's preliminary testing, RE Methylphen does not contain the same amounts of those ingredients as Prosed. (Compl. ¶¶ 1, 9.) In addition, Plaintiff alleges that Defendant has failed to include the disclaimer located on Defendant's website, which states that "even when a River's Edge product is labeled as containing the same active ingredients, they may be subject to different potency and dissolution specifications." Plaintiff contends that Defendant intentionally omitted this disclaimer in its marketing materials because it knows that such a statement will prevent RE Methylphen "from being listed as a generic of Prosed," in the drug data publishing books and in other drug formularies. (Compl. ¶ 13.) Courts have found that claims of false or misleading comparisons in the marketing or advertising of a drug product are actionable under the Lanham Act and not precluded by the FDCA. For instance, the court in *Ethex*, explained that claims involving "false descriptions . . . 'of specific or absolute

[5] However, the Court notes that the court in *Straus* highlighted that the FDA, in an amicus brief filed in *Florida Breckenridge, Inc. v. Solvay Pharmaceutical Inc.*, No. 97-8417-CIV-RYSKAMP, 1998 WL 468753 (S.D. Fla. Mar. 18, 1998), has urged that the definitions of equivalence for unapproved drugs be consistent with the FDA definitions of such term as used for approved drugs to prevent consumer confusion. 273 F. Supp. 2d at 793.

characteristics of a product . . . based on product testing' are actionable" Lanham Act claims. *See* 228 F. Supp. 2d at 1055 (permitting plaintiff to proceed with a claim that defendant falsely advertised its drug product as possessing B3 when it only contained B6 and B12). Similarly, in *Straus*, the court held that claims of false or misleading comparison of products in commercial advertisements did not invade the FDA's jurisdiction and explained that if a drug manufacturer claims that its drug has "the same active ingredients in the same amount" as another drug, then "the consumer and competitors have a right to expect that such representations have factual support and the Lanham Act provides a vehicle to enforce that expectation." 273 F. Supp. 2d at 793; see also *Pediamed*, 419 F. Supp. 2d at 729 (denying summary judgment of plaintiff's allegation that defendant's advertisements to drug wholesalers inviting them to compare the active ingredients of its drug product to plaintiff's was false or misleading because plaintiff claimed that defendant's product had "different amounts of active ingredients and [] different specification ranges"). The *Straus* court also indicated that a plaintiff's allegation that a defendant had falsely or misleading marketed its product as an "alternative" to the plaintiff's product is "less problematic" in interfering with FDA territory than claims asserting that the products are equivalent. *See Id.* at 793 n.143 (citing *In re Genetech, Inc. Sec. Litig.*, No.C-88-4038-DJ, 1989 WL 106834, at *2 (N.D. Cal. July 7, 1989) (explaining that if the FDA had primary jurisdiction over every complex pharmaceutical issue, then the FDA would have "no time to regulate drugs").

Thus, Plaintiff's allegation that Defendant has marketed RE Methylphen as a lower cost alternative to Prosed does not present the type of claim that other courts have found to be precluded by the FDA or its implementing regulations because it does not appear to require the Court to make any interpretation or application of the FDA's implementing regulations, absent

any evidence to the contrary. However, although Plaintiff will ultimately have to demonstrate how Defendant's representation of RE Methylphen as an alternative to Prosed is actually false or misleading to the audience that Defendant has allegedly targeted in its marketing of RE Methylphen. Similarly, Plaintiff's allegation that Defendant has marketed RE Methylphen as containing the same active ingredients in the same amounts as Prosed appears to assert the same type of Lanham Act claim that courts, including this one, have held do not create a potential interference with the FDA's exclusive jurisdiction, as far as can be determined from the face of Plaintiff's Complaint.

Defendant takes issues with Plaintiff's failure to set forth the standard that Plaintiff will use to demonstrate that the two drug products possess significantly different amounts of the same active ingredients. As Defendant has acknowledged, courts have allowed plaintiffs to allege that "defendant's label explicitly claims something that is provably false" under clearly established FDA standards or guidelines as valid Lanham Act claims. (Def.'s Reply Mem. Supp. Dismiss 5) (citing *Sandoz*, 902 F.2d at 230.) Defendant argues that the FDA regulations, allows for "reasonable variations caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practices" provided that the variation is not "unreasonably large." 21 C.F.R. § 201.51(g) (2009). Defendant contends that "for most ingredients," some FDA regulation or the USP[6] standard will "provide the answer" of what is an "unreasonably large" variation and that if such a standard existed then Plaintiff would have so alleged in the Complaint. Defendant then argues that without the existence of an FDA based standard, courts have not allowed plaintiff's to use non-FDA standards as proof, and cites

[6] As explained in *Sirus Laboratories, Inc. v. Rising Pharmaceuticals, Inc.*, the USP, or United States Pharmacopiea, is "a not-for-profit organization entrusted by the FDA with establishing the standards that ensure the quality of medicines and other health care technologies," but it is "not part of the FDA" and is "not incorporated into" the FDA's rules and regulations. No. 03-C-6965, 2004 WL 51240, at *3 (N.D. Ill. Jan. 7, 2004). As held in *Sirus*, using a USP standard for a drug ingredient "is not a direct application or interpretation of the FDCA or FDA." *Id.*

Sandoz as support for this proposition. Plaintiff counters that other courts have in fact allowed parties alleging Lanham Act claims to rely on non-FDA standards to measure the truth or falsity of a defendant's commercial representations, and cites *Axcan*.

The Court need not resolve whether Plaintiff can rely on a standard outside of the FDA implementing regulations at this time. The Court does not yet know what standard Plaintiff will rely on in showing that the amount of active ingredients in each product is significantly different when accounting for an allowable range of dissolution of the ingredient during the processing and storage of the product, whether that standard will be based on clearly established FDA guidelines, or whether Plaintiff will have to turn to generally accepted industry standards. The Court believes that it would be inappropriate to require Plaintiff to explicitly state what standard it would rely on its Complaint, because developing such a standard must likely entails expert assistance and essentially goes to Plaintiff's ability to prove that Defendant's representations in its advertisements are false or misleading. Moreover, other courts considering a similar issue have found it wiser to allow plaintiffs to proceed with their Lanham Act claim beyond a 12(b)(6) motion, although this Court is willing to revisit the Defendant's preclusion argument at a later time. Accordingly, the Court is not prepared to conclude that the Plaintiff's Lanham Act claim is precluded by the FDA or its implementing regulations, at least at this early stage in the litigation, without a more developed factual record.

II. Sufficiency of the Pleading

At this stage in the litigation it is not necessary for a plaintiff to prove its case. Instead, a plaintiff only needs to set forth sufficient facts, such that as accepted as true, would entitle the plaintiff to the relief requested. Defendant seeks to dismiss the Plaintiff's Complaint because it fails to provide a copy of the advertisements at issue. The Court finds that it is sufficient for Plaintiff to describe the advertisements in the Complaint, which Plaintiff has stated are the

marketing materials of RE Methylphen included in the product label, packaging inserts, and elsewhere, which state that the Defendant's product contains the same amount of active ingredients as Prosed or that represent that Defendant's product is a lower cost alternative to Prosed. Nevertheless, the Court recognizes that Plaintiff will eventually have to provide these alleged advertising materials to prevail on its Lanham Act claim.

Moreover, at the hearing Plaintiff explained that it tests each batch of Prosed to ensure that it complies with a 90–110% specification range. Also, the test results attached to the Complaint at exhibit 2c indicate that Prosed contains 90–110% of the amount listed for each ingredient, while the amount of those ingredients in RE Methylphen ranged from 120–185%. As provided under Federal Rule of Civil Procedure 10(c), "a copy of a written instrument that is an exhibit to a pleading is part of the pleading for all purposes," and thus the court can properly consider exhibit 2c in ruling on the Defendant's 12(b)(6) motion. *Smith v. McCarthy*, 349 Fed. App'x 851, 856 (4th Cir. 2009). Therefore, the Court finds that Plaintiff's Complaint has sufficiently alleged the variation range of the percentage of the active ingredients contained in Prosed and RE Methylphen. In sum, the Court finds that Plaintiff has sufficiently pled facts that, if proven to be true, would entitle Plaintiff to relief under the Lanham Act.

CONCLUSION

For the reasons articulated above, the Court DENIES Defendant's Motion to Dismiss (Doc. No. 5). A separate Order shall follow this Memorandum Opinion.

August 6, 2010
Date

/s/
Alexander Williams, Jr.
United States District Court Judge